

§ 74.1206

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 20 percent.

Water-insoluble matter, not more than 0.2 percent.

1,4-Dihydroxyanthraquinone, not more than 0.2 percent.

2-Amino-*m*-toluenesulfonic acid, not more than 0.2 percent.

Subsidiary colors, not more than 5 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total color, not less than 80 percent.

(2) D&C Green No. 5 for use in coloring drugs shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 20 percent.

Water-insoluble matter, not more than 0.2 percent.

1,4-Dihydroxyanthraquinone, not more than 0.2 percent.

Sulfonated toluidines, total not more than 0.2 percent.

p-Toluidine, not more than 0.0015 percent.

Sum of monosulfonated D&C Green No. 6 and Ext. D&C Violet No. 2, not more than 3 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 80 percent.

(c) *Use and restrictions.* (1) D&C Green No. 5 may be safely used to color nylon 66 (the copolymer of adipic acid and hexamethylenediamine) and/or nylon 6[poly-(*ε*-caprolactam)]nonabsorbable surgical sutures for use in general surgery, subject to the following restrictions:

(i) The quantity of color additive does not exceed 0.6 percent by weight of the suture.

(ii) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(iii) If the suture is a new drug, an approved new drug application, under section 505 of the act, is in effect for it.

(2) D&C Green No. 5 may be safely used for coloring drugs generally, in-

21 CFR Ch. I (4-1-02 Edition)

cluding drugs intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Green No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 24284, June 4, 1982; 47 FR 27551, June 25, 1982, as amended at 59 FR 40805, Aug. 10, 1994]

§ 74.1206 D&C Green No. 6.

(a) *Identity.* The color additive D&C Green No. 6 is 1,4-bis[(4-methylphenyl)amino]-9,10-anthracenedione (CAS. Reg. No. 128-80-3).

(b) *Specifications.* The color additive D&C Green No. 6 for use in coloring externally applied drugs shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Volatile matter (at 135 °C), not more than 2.0 percent.

Water-soluble matter, not more than 0.3 percent.

Matter insoluble in carbon tetrachloride, not more than 1.5 percent.

p-Toluidine, not more than 0.1 percent.

1,4-Dihydroxyanthraquinone, not more than 0.2 percent.

1-Hydroxy-4-[(4-methylphenyl)amino]-9, 10-anthracenedione, not more than 5.0 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 96.0 percent.

(c) *Uses and restrictions.* The color additive D&C Green No. 6 may be safely used for coloring externally applied drugs in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Green No. 6 shall be certified in accordance with regulations promulgated under part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 47 FR 14146, Apr. 2, 1982; 47 FR 24278, June 4, 1982; 51 FR 9784, Mar. 21, 1986]

§ 74.1208 D&C Green No. 8.

(a) *Identity.* (1) The color additive D&C Green No. 8 is principally the trisodium salt of 8-hydroxy-1,3,6-pyrene-trisulfonic acid.

(2) Color additive mixtures for use in externally applied drugs made with D&C Green No. 8 may contain only those diluents that are suitable and that are listed in part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Green No. 8 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practices:

Volatile matter (at 135 °C), not more than 15 percent.
 Water-insoluble matter, not more than 0.2 percent.
 Chlorides and sulfates (calculated as sodium salt), not more than 20 percent.
 The trisodium salt of 1,3,6-pyrenetrisulfonic acid, not more than 6 percent.
 The tetrasodium salt of 1,3,6,8-pyrenetetrasulfonic acid, not more than 1 percent.
 Pyrene, not more than 0.2 percent.
 Lead (as Pb), not more than 20 parts per million.
 Arsenic (as As), not more than 3 parts per million.
 Mercury (as Hg), not more than 1 part per million.
 Total color, not less than 65 percent.

(c) *Uses and restrictions.* D&C Green No. 8 may be safely used in externally applied drugs in amounts not exceeding 0.01 percent by weight of the finished product.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Green No. 8 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1254 D&C Orange No. 4.

(a) *Identity.* (1) the color additive D&C Orange No. 4 is principally the sodium salt of 4-[(2-hydroxy-1-naphthalenyl)azo]benzenesulfonic acid.

(2) Color additive mixtures for use in externally applied drugs made with D&C Orange No. 4 may contain only those diluents that are suitable and that are listed in part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Orange No. 4 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice.

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.
 Water-insoluble matter, not more than 0.2 percent.
 2-Naphthol, not more than 0.4 percent.
 Sulfanilic acid, sodium salt, not more than 0.2 percent.
 Subsidiary colors, not more than 3 percent.
 4,4'-(Diazoamino)-dibenzenesulfonic acid, not more than 0.1 percent.
 Lead (as Pb), not more than 20 parts per million.
 Arsenic (as As), not more than 3 parts per million.
 Mercury (as Hg), not more than 1 part per million.
 Total color, not less than 87 percent.

(c) *Uses and restrictions.* D&C Orange No. 4 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Orange No. 4 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 52396, Sept. 30, 1977, as amended at 43 FR 14642, Apr. 7, 1978; 46 FR 8461, Jan. 27, 1981]

§ 74.1255 D&C Orange No. 5.

(a) *Identity.* (1) the color additive D&C Orange No. 5 is a mixture consisting principally the sodium salt of 4',5'-dibromofluorescein (CAS Reg. No.